



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,121	01/18/2002	Randolph M. Howes	2514-0051-01	7866

22852 7590 12/03/2003

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
LLP  
1300 I STREET, NW  
WASHINGTON, DC 20005

EXAMINER
----------

CHOI, FRANK I

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 12/03/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/050,121

Applicant(s)

HOWES, RANDOLPH M.

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 5, 11, 17-28 and 30-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10, 12-16 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13, 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morrow (US Pat. 5,674,537).

Morrow expressly discloses singlet oxygen falling within the scope of applicant's claims (Column 1, line 64, Column 2, line 12, Column 4, lines 65-68, Column 5, lines 1-3 ).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (in product-by-process claims, patentability of a product does not depend on its method of production); *In re Brown*, 173 USPQ 685, 688 (CCPA 1972) (where the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter,

Art Unit: 1616

the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Claim 13 is directed to singlet oxygen. As indicated above, the patentability of a product does not depend on its method of production. Applicant's arguments are directed to difference in process and do not appear to show that the singlet oxygen produced by its process is any different from the singlet oxygen in Morrow.

Claims 1-4, 6-10, 12-16, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the acknowledged prior art in view of Beattie et al. (US Pat. 5,364,344).

Applicant acknowledges that singlet oxygen is effective against tumor cells and cancer (Paragraph 009). Further, it is acknowledge that the photodynamic method for producing singlet oxygen has several drawbacks, including the problem of untargeted portions of the body being exposed and expense (Paragraphs 013,014,015). It is disclosed that using a peroxide-hypochlorite anion system singlet oxygen is produced which is identical to that obtained by dye-sensitized photooxidation. (Paragraph 017). It is acknowledged that singlet oxygen is the principle bacterial oxidizing agent employed by human neutrophil and monocyte phagosome (Paragraph 019). Applicant acknowledges that singlet oxygen is a very short-lived species of oxygen (Paragraph 084).

McCaughan teaches that the photodynamic reaction was discovered by observing the effects of light on dyes (pg. 50).

Schraufstatter et al. teach that both hypochlorite and hydrogen peroxide have toxic effect on tumor cells by different mechanisms (Abstract).

Beattie et al. teach the use dual lumen catheters for delivering different fluids into the blood stream (See entire document).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of sodium hypochlorite and hydrogen peroxide to treat tumors. However, the prior art amply suggests the same as it is known in the art that hypochlorites and peroxides are effective in treating tumor cells and that they also react to form singlet oxygen which is also effective against cancer and tumor cells. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would be effective in treating tumors. One of ordinary skill in the art, knowing that singlet oxygen is a short-lived species, would be motivated to separately combine the peroxide and hypochlorite at the point of use so as to ensure that singlet oxygen is available for treatment of the cancer or tumor cell. Also, one of ordinary skill in the art would expect that that by use of a dual lumen catheter the peroxide and hypochlorite could be kept separate until the last possible moment thereby ensuring the maximum concentration of singlet oxygen possible. Further, one of ordinary skill in the art would expect that simultaneous or sequential administration would be effective in treating tumors. See *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959) (obvious to reverse order of prior art process steps); See also *In re Burhans*, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

Art Unit: 1616

Examiner has duly considered Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

December 1, 2003



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600